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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/611,257	07/06/2000	Terrance P. Snutch	381092000721	5449

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MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER

KOLKER, DANIEL E

ART UNIT PAPER NUMBER

1649

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/611,257

Applicant(s)

SNUTCH ET AL.

Examiner

Daniel Kolker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,14 and 18-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6 and 19-26 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1 – 2, 4 – 6, 14, and 18 – 26 are pending and under examination.

Withdrawn Rejections

4. The rejections set forth under 35 USC §§ 101 and 112 are withdrawn. The claimed nucleic acids are asserted to encode alpha G1 subunits of T-type calcium channels. SEQ ID NO:24 is the rat calcium channel subunit (specification, paragraph spanning pp. 11 – 12). SEQ ID NO:37 is the human sequence (see specification p. 22, note amendment to specification filed 15 September 2004). The specification asserts that the claimed channels are useful for screening for drugs for treatment of many diseases, including epilepsy (see specification, p. 9 line 24).

The prior art recognized importance of T-type channels in epilepsy. See for example Lee et al. (1999. Journal of Neuroscience 19:1912-1921, particularly final paragraph on p. 1920). Coulter et al. (1989. Annals of Neurology 25:582-593) teach that the anti-convulsant drugs ethosuximide and dimethadione both decrease activity of T-type calcium channels. The specification discloses that the proteins encoded by the claimed nucleic acids pass calcium in a manner that is consistent with their being T-type calcium channels. See for example specification pp. 20 and 23 as well as Figures 3, 4, and 7. Thus the data presented in the specification support the assertion that the claimed nucleic acids encode T-type calcium channels.

The proteins of SEQ ID NO:24 and 37 are 91% identical to each other and are similar to other prior art proteins. U.S. Patent 6,358,706 (filed 22 October 1999, issued 19 March 2002) discloses SEQ ID NO:5, which is 91% identical to instant SEQ ID NO:24 and 99% identical to instant SEQ ID NO:37. The '706 patent discloses that T-type calcium channels have "important consequences for epilepsy" and the patent states that modulators of the channels found in screening assays can be candidates for treatment of epilepsy (see column 17). Additionally the calcium currents passed by these channels are sensitive to the known anti-convulsant ethosuximide (see column 27 line 55). Perez-Reyes et al. (1998 Nature 391:896 – 906, of

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record) teach a rat alpha 1G subunit with the sequence deposited as GenBank accession number AF027984. The sequence is 99.8% identical to instant SEQ ID NO:24 and is 91.9% identical to instant SEQ ID NO:37. The reference teaches that alpha 1A calcium channels, when mutated, lead to epileptic phenotypes (see p. 896 second column).

For the reasons set forth above, the asserted utility for the claimed invention, namely using the nucleic acids in screening assays to find candidates for treatment of epilepsy, constitutes a specific and substantial credible utility. Thus the rejection is withdrawn.

New rejections and Objections

Claim Objections

5. Claim 14 is objected to because of the following informalities: it has a typographical error. It reads "n isolated" but should read "An isolated". Appropriate correction is required.

Claim Rejections - 35 USC § 101

6. Claims 1 – 2, 4 – 6, and 19 – 25 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim is drawn to a recombinant DNA molecule which comprises nucleic acid sequences encoding either SEQ ID NO:24 or 37. The claim requires that said sequence be operably linked to control sequences to effect its expression. Genomic DNA molecules residing within an animal are operably linked to control sequences called promoters and enhancers. The recitation of "recombinant" is a product-by-process limitation which does not distinguish the claimed invention over the naturally occurring products. Amendment of claim 1 to recite "An isolated DNA" is recommended.

Claim Rejections - 35 USC § 102

7. Applicant is reminded that the effective filing date for all pending claims is 6 July 2000 for the reasons set forth in the office action mailed 21 December 2004. Applicant did not traverse the examiner's conclusion of the effective filing date.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 4 – 6, 14, and 19 – 26 are rejected under 35 U.S.C. 102(a) as being anticipated by McRory et al. (1999. Society for Neuroscience Abstracts 25(1-2):197. Presented at 29th Annual Meeting of the Society for Neuroscience October 23 – 28 1999).

The claims encompass isolated nucleic acids, recombinant DNA molecules, cells, and methods of effecting production wherein the nucleic acid encodes SEQ ID NO:24. The specification discloses that SEQ ID NO:24 is rat calcium channel alpha 1G subunit (specification, paragraph spanning pp. 11 – 12). McRory teaches isolation and characterization of nucleic acids encoding several rat calcium channel subunits, including alpha 1G. Furthermore the reference teaches expressing the nucleic acids in HEK 293 cells, which are mammalian cells. The expression is sufficient to effect production of the protein, as the reference teaches that it allows the determination that the nucleic acid encodes a functional alpha 1G subunit. While the reference is silent with respect to the sequence of the rat nucleic acid and protein, the products disclosed in the reference are indistinguishable from the claimed invention.

Conclusion

9. Claims 1 – 2, 4 – 6, 14, and 19 – 26 are rejected.

Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.

April 7, 2006


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER